

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ASHLEY PUGH, <i>et al.</i> ,	:	
Plaintiffs,	:	
	:	
v.	:	Civil No. 5:20-cv-00630-JMG
	:	
COMMUNITY HEALTH SYSTEMS, INC., <i>et al.</i> ,	:	
Defendants.	:	

MEMORANDUM OPINION

GALLAGHER, J.

July 7, 2023

Plaintiffs Ashley Pugh and Daniel Pugh, individually and as parents and guardians of Minor-Plaintiff Sean Pugh bring professional negligence/medical malpractice claims against Northampton Hospital Company, LLC d/b/a/ Easton Hospital (“Easton Hospital”); Northampton Clinic Company, LLC d/b/a Easton Area Obstetrics & Gynecology Associates (“EAOG”); and Douha Sabouni, M.D. *See* Am. Compl., ECF No. 80. Plaintiffs allege Defendants committed medical negligence during the birth of Mrs. Pugh’s son, Sean Pugh. As a result of Defendants’ negligence, Plaintiffs allege Sean suffers various injuries, including hypoxia and HIE-related brain damage, neurodevelopmental abnormalities of autism and other impairments, and pain and suffering.

On February 3, 2023, Defendants moved for summary judgment in connection with a *Daubert* motion to preclude Plaintiffs’ expert from opining on the general and specific causes of Sean Pugh’s autism. The Court granted Defendants’ *Daubert* motion. The Court also deferred from ruling on Defendants’ motion for summary judgement and directed the Parties to provide supplemental briefing on Plaintiffs’ remaining causation evidence. Now before the Court is

Defendants' Motion for Summary Judgment for Lack of Causation (ECF No. 125). For the following reasons, Defendants' Motion for Summary Judgment is granted.

1. FACTUAL BACKGROUND

a. Plaintiffs' Factual Allegations and Claims

Plaintiffs Ashley Pugh and Daniel Pugh, individually and as parents and guardians of Sean Pugh bring medical malpractice and negligence claims against Defendants Easton Hospital, EAOG, and Dr. Sabouni. *See* Am. Compl., ECF No. 80. Plaintiffs allege Defendants acted negligently when providing services to Mrs. Pugh during her delivery of Sean.

In late 2013, Mrs. Pugh was twenty-six years old and pregnant with her first child. ECF No 80 ¶19. Mrs. Pugh attended EAOG for routine check-ups, including an ultrasound. *Id.* ¶¶19-20. On January 7, 2014, while Mrs. Pugh was thirty-two weeks and five days into gestation, the ultrasound indicated Mrs. Pugh's baby maintained a "normal" fetal heart rate (FHR) of 141 beats per minute (BPM). *Id.* ¶¶21-22.

On January 22, 2014, Mrs. Pugh went to Easton Hospital after experiencing a partial rupture of membranes and intermittent leaking. *Id.* ¶23. Mrs. Pugh was admitted to Easton Hospital and went into labor. *Id.* ¶24. Throughout the day, Mrs. Pugh was tended to while in labor. *Id.* ¶¶28-36. Defendant Dr. Sabouni began caring for Mrs. Pugh. *Id.* ¶36. At 7:00 p.m., Plaintiffs allege, Dr. Sabouni, "stated that she would let Mrs. Pugh 'continue to push until 9:00 p.m.' and 'then do a c-section.'" *Id.* ¶39. Defendants noted Mrs. Pugh became increasingly tired. *Id.* ¶¶41-47. At 9:00 p.m., Mrs. Pugh alleges she asked for the c-section Dr. Sabouni referenced earlier and Dr. Sabouni responded, "You're close, you can get him out." *Id.* ¶48.

Plaintiffs allege an Obstetrics (OB) Provider Progress Note at 9:30 p.m. showed the following message: "Impression: non reassuring fetal heart rate." *Id.* ¶53. The same note provides:

“patient was pushing from 7 till 8 o’clock then felt tired. . . . Stop pushing from 8 till 8:30 then restart pushing [FHR] cat 2 variable decelerations and at 9:39 sec[ond] to maternal exhaustion [c-section] was called while preparing for [c-section] patient was feeling urge and was pushing.”

Id. ¶54. Dr. Sabouni called for a cesarean delivery (c-section) and directed Mrs. Pugh to continue pushing until the operating room (OR) team assembled. *Id.* ¶55. The detectable FHR increased to 175, with baseline changes of “tachycardia.”¹ By 10:30 p.m., no c-section team had assembled to deliver Mrs. Pugh’s baby. *See id.* ¶¶61-62. The FHR had decreased to a baseline rate of 165. *Id.* ¶62. Mrs. Pugh continued to push. *Id.* ¶62. At 10:42 p.m., the baby’s FHR had decreased to a baseline rate of 145. *Id.* ¶63. Baby Sean was delivered at 10:43 p.m. at thirty-five weeks. *Id.* ¶64. Sean was born at a weight of five pounds and ten ounces; he was in “profound stress; his body was limp and without a heart rate; he had no first gasp or respiration; and he maintained Apgar scores of “0” during his first one to ten minutes of life.² Sean’s heart rate went undetected until he was

¹ *Id.* ¶57. The Court understands “tachycardia” to mean “relatively rapid heart action.” *See Fetal Tachycardia*, CINCINNATI CHILDREN’S HOSPITAL, <https://www.cincinnatichildrens.org/health/f/fetal-tachycardia#:~:text=Fetal%20tachycardia%20is%20a%20type,above%20180%20BPM%20at%20times> (last updated January 2023).

² *Id.* ¶¶65-68. An Apgar score “is a test given to newborns soon after birth.” *What is the Apgar Score?*, NEMOURS CHILDREN’S HEALTH, <https://kidshealth.org/en/parents/apgar0.html> (last reviewed February 2018). “This test checks a baby’s heart rate, muscle tone, and other signs to see if extra medical care or emergency care is needed.” *Id.* “Babies usually get the test twice: [one] minute after birth, and again [five] minutes after they’re born.” *Id.* “If there are concerns, a baby may get the test again.” *Id.* The Apgar scores five things on a scale of zero [0] to two [2], with 2 [two] being the best score. *Id.* The five factors Apgar scores are: appearance (skin color), pulse (heart rate), grimace response (reflexes), activity (muscle tone), and respiration (breathing rate and effort). *Id.* “Doctors, midwives, or nurses [then] add up these five factors” to produce an Apgar score between ten and zero. *Id.* Apgar scores of zero would indicate the baby presents: bluish-gray or pale all over, no pulse, no response to stimulation, no movement, no breathing. *Id.* “A slightly low score (especially at [one] minute) is common,” but there may be concerns if a baby’s score does not improve at the five-minute test. *Id.*

twenty minutes of age. *Id.* ¶70. A neurologist then explained to Mr. and Mrs. Pugh “Sean had suffered fetal acidemia and hypoxemia” and would be transferred to Lehigh Valley Hospital.³

Plaintiffs further allege “[a]n MRI five days after Sean’s birth showed brain damage, and liver [and] kidney damage.” ECF No. 80 ¶76. And a later “MRI showed ‘hypoxic ischemic injury.’” *Id.* ¶78. Hypoxic ischemic injury such as hypoxic ischemic encephalopathy (HIE) “is a type of brain dysfunction (brain injury) that occurs when the brain experiences a decrease in oxygen or blood flow” and “can occur before birth, during labor and delivery or after birth.”⁴ Sean spent many weeks in various hospitals. ECF No. 80 ¶77, 80. On March 12, 2014, Sean was discharged “with a diagnosis of ‘severe perinatal asphyxia [or the failure to establish breathing at birth] with multisystem involvement’ and ‘global developmental delay.’”⁵

Plaintiffs allege Defendants acted negligently and/or carelessly while providing services to Mrs. Pugh during her delivery, which led to Sean Pugh’s resulting injuries, including, *inter alia*: “fetal acidemia; hypoxemia; permanent developmental delay and cognitive impairment; speech and behavioral pathology; autism; physical growth impairment; cardiac murmur; dilated aortic root;

³ *Id.* ¶72. Hypoxia is “[l]ow levels of oxygen in the tissues.” Patricia A. Heale, *Fetal Monitoring and Umbilical Cord Gases: What’s the Secret?*, TEXAS CHILDREN’S HOSPITAL, https://www.texaschildrens.org/sites/default/files/uploads/documents/health_professionals/kaleidoscope/Day%20201%20Fetal%20Monitoring%20and%20Umbilical%20Cord%20Gases.pdf. And acidemia is a “state of low blood pH.” *Id.*

⁴ *Hypoxic Ischemic Encephalopathy: Causes and Symptoms*, MASS GENERAL FOR CHILDREN (Mar. 1, 2022), [https://www.massgeneral.org/children/hypoxic-ischemic-encephalopathy#:~:text=Hypoxic%20ischemic%20encephalopathy%20\(HIE\)%20is,an%20delivery%20or%20after%20birth](https://www.massgeneral.org/children/hypoxic-ischemic-encephalopathy#:~:text=Hypoxic%20ischemic%20encephalopathy%20(HIE)%20is,an%20delivery%20or%20after%20birth).

⁵ *Id.* ¶780; see also *Perinatal Asphyxia*, WORLD HEALTH ORG., <https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/newborn-health/perinatal-asphyxia#:~:text=Birth%20asphyxia%20defined%20as%20the,causes%20of%20early%20neonatal%20mortality>. (last visited May 8, 2023).

physical and emotional pain and suffering; aggravation and/or exacerbation of all known and unknown pre-existing medical conditions; and a severe shock to his entire nervous system.” ECF No. 80 ¶87.

Plaintiffs and Defendants’ expert physicians agree Sean has been diagnosed with autism/autism spectrum disorder (“ASD”).⁶ And Defendants’ experts acknowledge Sean’s various conditions upon birth, including Sean’s medical records of a HIE diagnosis, ECF No. 132-1, Enns Dep. Tr. 19: 1-15, 20:6-14; ECF No 132-2, Volkmar Dep. Tr. 32:3-10; Sean’s diagnosis of “an extremely high risk for severe neuro-developmental delays,” ECF No. 132-1, Enns Dep. Tr. at 22:13-22; and Sean’s Apgar scores, limp appearance, and undetectable heart rate at and following birth, *id.* at 9:10-22, ECF No. 132-2, Volkmar Dep. Tr. 31:5-24. Moreover, Defendants’ expert agrees Sean has been documented to have intellectual disabilities. ECF No. 132-1, Enns Dep. Tr., 27:13-15.

b. Pretrial Motions

Presently in front of the Court is Defendants Easton Hospital, EAOG, and Dr. Sabouni’s Motion for Summary Judgment. In sum, Defendants aver summary judgment is warranted because Plaintiffs do not sufficiently proffer expert opinion and testimony concerning Defendants’ causation of Sean’s alleged resulting injuries. And, more specifically, Defendants contend the Court’s preclusion of Plaintiffs’ expert on causation, Dr. Mulkey, renders Plaintiffs without adequate expert opinion on causation and injuries in this matter. Accordingly, the Court will provide an overview of Dr. Mulkey’s expert testimony and opinion and its preclusion by the Court before providing information concerning the present motion for summary judgment.

⁶ ECF No. 125 at 2-3 (conceding Sean has been diagnosed with autism). The Court notes “Autism Spectrum Disorder is a term that refers to a wide variety of autism; it is the clinical definition for autism.” ECF No. 118 at 10 n. 5. So the Court uses the terms interchangeably.

i. Defendants' *Daubert* and Summary Judgment Motions Concerning Plaintiffs' Expert Dr. Mulkey's Causation Testimony and Opinion

On February 3, 2023, Defendants Easton Hospital and EAOG moved to preclude Plaintiffs' causation testimony regarding the alleged cause of Sean Pugh's autism under *Daubert*. *See generally* ECF No. 125. More specifically, Easton Hospital and EAOG moved to preclude Plaintiff's expert on causation, Dr. Sarah Mulkey because, Defendants averred, Dr. Mulkey "is the only Plaintiffs' expert that opines on causation in this matter."⁷ Defendant Dr. Sabouni also moved to preclude Plaintiffs' expert from offering any causation testimony regarding the alleged cause of Sean Pugh's autism.⁸ Like Easton Hospital and EAOG's *Daubert* motion, Dr. Sabouni's moved to preclude Dr. Mulkey's causation testimony as Plaintiffs' "sole causation expert."⁹ Defendants did not contest Dr. Mulkey's qualifications as an expert. Defendants averred the Court's precluding of Dr. Mulkey's causation opinion warrants granting Defendants' request for summary judgment because "Plaintiff can no longer (1) prove that autism as the result of Defendants' negligence caused [Sean Pugh's] current disabilities or (2) that some other process solely caused [Sean Pugh's] current disabilities [because] autism/ASD can account for all of [Sean Pugh's] disabilities." ECF No. 125 at 19.

Dr. Mulkey provided one expert report and two supplement reports in total. In Dr. Mulkey's September 29, 2021 expert report, Dr. Mulkey opines, *inter alia*, Sean experienced perinatal

⁷ ECF No. 125 at 12. Relatedly, Easton Hospital and EAOG also moved for summary judgment for lack of causation. *See generally* ECF No. 125.

⁸ ECF No. 118 at 2. And, and in the alternative, Dr. Sabouni requested a *Daubert* hearing. *Id.*

⁹ ECF No. 118 at 7. Dr. Sabouni also moved to adopt and incorporate Easton Hospital and EAOG's related *Daubert* and summary judgment motion. *See generally* ECF No. 126. And, relatedly, Dr. Sabouni moved to join Easton Hospital and EAOG's supplemental briefing to their *Daubert* motion. *See generally* ECF No. 139.

hypoxia-ischemia encephalopathy (HIE) at birth, which causes his “abnormal neurodevelopmental outcome of autism.” ECF No. 125-9 at 10. Dr. Mulkey further provides “Sean’s significant presentation of severe neonatal encephalopathy and the absence of more severe placental findings[] . . . [supports a finding] the cause of his autism outcome is the perinatal hypoxia-ischemia, although a contribution from the prolonged rupture of membranes is possible, but is not a main cause.”¹⁰ So, “[h]ad [Sean] avoided HIE, his outcome would be normal.” *Id.* Dr. Mulkey provided she reviewed Sean’s medical records and relevant medical literature, and utilized her “education, experience, and general knowledge of the literature and [her] field of medicine” to form an opinion on the present action. *Id.* More specifically, Dr. Mulkey cites two studies in her expert report as “[a] sample of the reported increased risk for autism associated with HIE” in medical literature. *Id.* First, “. . . a nested case-control study, [finding] children with perinatal ischemic-hypoxic conditions had an increased odds of developing autism spectrum disorders.”¹¹ And second, “. . . a population-based

¹⁰ *Id.* The Court notes “Neonatal encephalopathy [(NE)] is clinically defined as a syndrome characterized by disturbed neurologic function occurring in the earliest days of an infant born at or beyond 35 weeks of gestation.” ECF No. 118 at 7-8. At Dr. Mulkey’s discovery deposition on September 21, 2022, she provided the preferred term for HIE is NE because there are different presentations of NE that may be for reasons other than HIE. *See* ECF No. 125-12, Mulkey Dep. Tr. 46:2-22. So “neonatal encephalopathy is . . . the big umbrella term under which there are babies that have neonatal encephalopathy because of hypoxia ischemia.” *Id.*

¹¹ *Id.* (citing Darios Getahun, et al., *Association of Perinatal Risk Factors with Autism Spectrum Disorder*, 34 AMERICAN JOURNAL OF PERINATOLOGY 295 (2017)). Dr. Mulkey reviewed and referenced a 2017 study titled “Association of Perinatal Risk Factors with Autism Spectrum Disorder” (“Getahun Study”). Ex. 3(a), ECF No. 132-3 at 2. The Getahun Study sought “[t]o examine the association between exposure to perinatal factors and autism spectrum disorders (ASD).” *Id.* the study “examine[d] the association between perinatal conditions and ASDs in singleton live-born children delivered in a large health maintenance organization.” *Id.* at 3. “The study population was drawn from a total of 594,638 births between 1991 and 2009.” *Id.* “. . . [T]he final population consisted of 401,660 singleton, live born children.” *Id.* The study then compared “[d]ifferences in maternal and child characteristics between children with and without ASDs.” *Id.* at 4. The study found “children exposed to perinatal conditions were more likely to be diagnosed with ASD than those who were not exposed.” *Id.* at 8. More specifically, researchers found “intrapartum conditions . . . [including birth asphyxia] to be significant risk factors for ASD at term birth.” *Id.* And “[m]ost of the perinatal conditions-associated increase in ASDs risk is attributable to exposure to birth asphyxia with Apgar score < 7 at 5 minutes (46%)” *Id.* So “children who

study of moderate to severe neonatal encephalopathy, [finding] children with neonatal encephalopathy were 5.9 times more likely to be diagnosed with autism than controls.”¹²

Dr. Mulkey expanded on her causation opinions in two supplemental expert reports. First, Dr. Mulkey’s February 4, 2022 supplemental report analyzed Sean’s January 28, 2022 brain MRI. ECF No. 125-10 at 2. Dr. Mulkey then found “the brain MRI findings of white matter injury that he has . . . is consistent with the sequelae of the acute HIE he had on his brain MRI at [five] days of age.” *Id.* And, Dr. Mulkey opined, Sean “has an abnormal neurodevelopmental outcome due to this injury.” *Id.*

Second, Dr. Mulkey’s July 30, 2022 supplemental report provided opinions in response to her review of other expert reports. *See* ECF No. 125-11 at 2. Notably, Dr. Mulkey provides “[A]utism is a multi-factorial complex neurodevelopmental disorder the cause of which can relate to a genetic condition or a multitude of other risk factors” *Id.* Dr. Mulkey then provides

had birth asphyxia, Apgar score < 7 at 5 minutes and resuscitation clearly are at increased risk of ASD.” *Id.* The study concluded “perinatal conditions, especially birth asphyxia and preeclampsia, are associated with increased risk of childhood ASD even after accounting for gestational age at delivery and other potential confounding factors.” *Id.* at 9.

¹² ECF No. 125-9 at 10 (citing Nadia Badawi et al., *Autism following a history of newborn encephalopathy: more than a coincidence?*, 48 DEVELOPMENTAL MEDICINE & CHILD NEUROLOGY 85 (2006)). The study included children with moderate or severe newborn encephalopathy (NE) shown by the following criteria: seizures, or “any two of the following lasting for longer than [twenty-four hours]: [a]bnormal consciousness, [d]ifficulty maintaining respiration . . . , [d]ifficulty feeding . . . , [a]bnormal tone and reflexes.” ECF No. 132-4 at 3. The Badawi study involved “a population-based study of NE term-born infants” at least 37 weeks’ gestation.” *Id.* Researchers compared infants with moderate or severe NE with “564 randomly selected term controls” or infants.” *Id.* The study ultimately found “an unexpected but strong association between moderate and severe newborn encephalopathy (NE) and a subsequent diagnosis of autism.” *Id.* More specifically, “[c]ompared with the controls, the children who had experienced NE were 5.9 times (95% confidence interval 2.0-16.9) more likely to have been diagnosed with ASD.” *Id.* at 2. The researchers concluded their “. . . population-based case-control study has highlighted a strong association between moderate to severe term NE and the development of ASD.” *Id.* at 5. Nevertheless, researchers conceded, “[g]iven the small number of cases involved, it is not clear from our findings what the association between NE and autism may represent.” *Id.*

various citations to studies finding an association or increased risk between HIE and the development of ASD.¹³ Thus Dr. Mulkey finds “infants who have abnormal perinatal exposures including NE or HIE and requirement of NICU level care have an increased risk of ASD.” *Id.* At 2-3. And, once again, “[h]ad [Sean Pugh] not had the condition of HIE at birth, he would not have developed ASD.” *Id.* at 3. Dr. Mulkey also provided “[h]ad [a] caesarean section delivery been expedited when called at 2130 and Sean Pugh been delivered close to 2130, he more likely than not would not have had severe HIE-NE and would have had a much better and likely normal outcome.” *Id.* at 5.

On February 3, 2023, Defendant Dr. Sabouni moved to preclude Dr. Mulkey’s opinion Sean Pugh’s autism was caused by the perinatal hypoxia-ischemia. Dr. Sabouni contended Dr. Mulkey cannot reliably opine as to whether or not HIE actually causes autism because she only finds an association between HIE and autism. ECF No. 118 at 10. And, furthermore, Dr. Mulkey cannot reliably “raise[] the possibility that Ms. Pugh’s prolonged rupture of membranes may **possibly** be the cause of Sean Pugh’s autism.” *Id.* at 11. So, in sum, Dr. Sabouni’s *Daubert* motion concerned the reliability of Dr. Mulkey’s opinions on causation. *See id.*

On February 3, 2023, Defendants Easton Hospital and EAOG also moved to exclude Plaintiffs’ causation testimony regarding the alleged cause of minor Plaintiff’s autism and summary judgment for lack of causation. *See generally* ECF No. 125. In sum, Defendants contended Dr. Mulkey’s conclusions Sean’s “autism was caused by neonatal encephalopathy/hypoxic ischemic encephalopathy (NIE/HIE) are unreliable under the case law and state of medical literature.” ECF

¹³ *Id.* (providing the following citations, *inter alia*: Neonatal Encephalopathy and Neurologic Outcome, *Executive Summary*, 2nd Ed., 2014; Nadia Badawi et al., *Autism following a history of newborn encephalopathy: more than a coincidence?*, 48 DEVELOPMENTAL MEDICINE & CHILD NEUROLOGY 85 (2006); Chalak LF, et al., *Ped Res* (2018); A. Winkler-Schwartz A et al., *Pediatr Neural* (2014)).

No. 125 at 4. And thus, Defendants submitted, Plaintiffs could not “establish that []NE/HIE[] generally causes autism or that . . . NE/HIE specifically caused [Sean Pugh’s] autism.” *Id.*

Plaintiffs responded in opposition to both *Daubert* motions with similar contentions.¹⁴ Plaintiffs averred, *inter alia*, Dr. Mulkey’s causation testimony is sufficiently reliable because studies support perinatal hypoxia/HIE are strongly associated with and/or increase the risk of autism. ECF No. 132 at 24. Plaintiffs contended Dr. Mulkey’s general causation argument is consistent with the lower burden for plaintiffs in medical malpractice actions concerning causation. *See* ECF No. 137 at 6-7. Plaintiffs also submitted “relevant case law . . . firmly support an inference that HIE/NE could have caused Sean’s autism.” ECF No. 132 at 41 (emphasis in original). So, “Dr. Mulkey’s causation opinions . . . rest on reliable methodologies and have reliable bases” *Id.* at 42.

On May 10, 2023, the Court (1) granted Defendant Dr. Sabouni’s motion to preclude any of Plaintiffs’ experts from offering causation testimony regarding the alleged cause of Sean Pugh’s autism at trial, and (2) granted in part Defendants Easton Hospital and EAOG’s *Daubert* motion to exclude Plaintiffs’ causation testimony regarding the alleged cause of minor Plaintiff’s autism. The Court also granted Dr. Sabouni’s motions to join Defendants Easton Hospital and EAOG’s *Daubert* and summary judgment motion. *See* ECF No. 159.

In sum, the Court found Dr. Mulkey’s methodology unreliable because Dr. Mulkey relied on “a ‘sample’ of the literature—which is consistent with Dr. Mulkey’s findings of an increased risk and/or association between HIE/NE and autism/ASD—as well as her ‘general knowledge of

¹⁴ *See generally* ECF Nos. 132, 137. Plaintiffs raised contentions similar in substance concerning all Defendants’ motions to preclude Dr. Mulkey’s causation testimony. Accordingly, the Court considered the motions in concert. *See* ECF No. 160 at 11 n. 15.

the literature’ to support her general causation/association opinion.” ECF No. 180 at 25 (citing ECF No. 125-9 at 10) (Dr. Mulkey September 29, 2021 expert report). The Court also found Dr. Mulkey’s general causation/association opinion insufficient because “Dr. Mulkey’s expert reports and related testimony do not show her methodology ‘consists[s] of a testable hypothesis,’ has been ‘subjected[ed] to peer review[,]’ nor has a ‘known or potential rate of error.’” *Id.* at 26 (citing *Daddio v. A.I. DuPont Hosp. for Child. of Nemours Found.*, 650 F. Supp. 2d 387, 403 (E.D. Pa. 2009), *aff’d sub nom. Daddio v. Nemours Found.*, 399 F. App’x 711 (3d Cir. 2010)). Accordingly, the Court then found Dr. Mulkey’s specific causation conclusion—that Defendants’ conduct in this case caused Sean’s autism/ASD outcome—to be “an unreliable ‘speculative leap’” without additional support and explanation. *Id.* at 28 (citing *Hoebling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 274 (E.D. Pa. 2021)). So, the Court granted Defendants’ *Daubert* motions and precluded Dr. Mulkey from providing “(1) a general causation opinion that HIE/NE increases the risk and/or causes autism/ASD, and (2) a specific causation opinion that Sean’s HIE/NE caused his autism/ASD in this case.” *Id.* at 32.

ii. Defendants’ Summary Judgment Motions

Defendants Easton Hospital and EAOG also moved for summary judgment in their *Daubert* motion concerning Dr. Mulkey’s causation opinion. ECF No. 125 at 17-19; *see also* ECF No. 126 (Defendant Dr. Sabouni moving to join Defendants Easton Hospital and EAOG’s *Daubert* and summary judgment motion). Easton Hospital and EAOG aver Plaintiffs would not have sufficient expert testimony without Dr. Mulkey’s causation opinion. ECF No. 125 at 18-19. And Defendants also submit Plaintiffs cannot show “that some other process solely caused [Sean Pugh’s] current disabilities since autism/ASD can account for all of [Sean Pugh’s] disabilities.” *Id.* Because, Defendants contend, “[t]here is no way to disentangle [Sean Pugh]’s intellectual functioning as the result of his autism diagnosis versus some other diagnosis or intellectual disability.” *Id.* at 19. On

the other hand, Plaintiffs aver the record supports Defendants proximately caused and/or increased the risk of Sean’s resulting injuries other than autism. ECF No. 132 at 42-43. And, Plaintiffs contend, Defendants do not contest Sean’s birth-related brain damage “caused him an extremely high risk for severe neuro developmental delays.” *Id.* at 43. And, furthermore, Plaintiffs point to Defendants’ own experts and contend “Defendants’ causation experts agree that Sean suffers intellectual disabilities and that perinatal hypoxia/HIE can cause neuro-developmental impairs.” *Id.* So, Plaintiffs aver, “[t]he record . . . [sufficiently] establishes that Defendants caused Sean’s birth-related brain damage (HIE), that Sean’s brain damage increased his risk of developing both autism and other neurodevelopmental disorders/delays . . . , and that Sean in fact developed both autism and other neurodevelopmental disorders.” *Id.* at 45.

On May 10, 2023, in the Court’s order granting Defendants’ *Daubert* motions, the Court also deferred ruling as to Defendants’ related summary judgment motion. The Court directed the Parties to provide supplemental briefing concerning the summary judgment motions. *See* ECF No. 159. More specifically, the Court directed the Parties to provide briefing concerning (1) whether Dr. Mulkey remained Plaintiffs’ sole causation expert, (2) whether the record supports any allegations Sean Pugh sustained injuries/harm independent of his autism diagnosis, and (3) whether or not the record supports Plaintiffs’ allegations Defendants’ negligence proximately caused or increased the risk of harm suffered by Sean Pugh. *Id.* at 2-3. Accordingly, the Parties provided supplemental briefing on the causation issues raised in Defendants’ summary judgment motions. *See* ECF Nos. 184, 185, 186.

In sum, Plaintiffs contend summary judgment is not warranted because, although Dr. Mulkey is Plaintiffs’ sole causation expert on the issue of Sean’s **autism causation**, Sean is entitled to damages concerning injuries independent of his autism diagnosis—including brain damage,

neurodevelopmental impairments of Attention-Deficit/Hyperactivity Disorder (ADHD) and other intellectual delays/deficits, and pain and suffering, and economic losses resulting from neurodevelopmental impairments—as supported by causation experts. ECF No. 186 at 1-2. Concerning the cause of Sean’s brain damage, Plaintiffs identify the following experts and other support in the record: Dr. Mulkey; MRI imaging; Jessie Aw-Zoretic, MB, ChB; Ie-Ming Shih, MD, PhD.; and Marc. H. Kobelin, MD. Plaintiffs then identified the following experts concerning Sean’s neurodevelopmental abnormalities separate and apart from autism: Dr. Mulkey, hospital consultation reports prepared by Sean’s medical providers, and two of Defendants’ experts, Jennifer L. Pacyon, Psy.D Dr. and William J. Barbaresi, MD.

On the other hand, Defendants Easton Hospital and EAOG and Defendant Dr. Sabouni submit summary judgment is warranted due to Plaintiffs’ insufficient expert causation opinions and testimony. *See generally* ECF Nos. 185, 184. Defendants contend Dr. Mulkey is Plaintiffs’ sole causation expert.¹⁵ Furthermore, Defendants aver the record does not support Plaintiffs’ allegations Sean Pugh sustained injuries and/or harm independent of his autism diagnosis. ECF No. 185 at 10; ECF No. 184 at 6. Defendants Easton Hospital and EAOG contend three of Plaintiffs’ experts opining on other medical conditions or diseases—particularly, Dr. Pacyon, Dr. Barbaresi, and Dr. Mulkey—do not provide causation opinions sufficient to support allegations of injuries independent of autism. *See* ECF No. 185 at 10-15. And Dr. Sabouni avers “Plaintiffs cannot offer any evidence to support general causation (i.e., that HIE causes any injury separate

¹⁵ *See e.g.*, ECF No. 184 at 4-5 (providing none of Plaintiffs’ medical experts outside of Dr. Mulkey offered causation testimony); ECF No. 185 (surveying Plaintiffs’ proffered experts and contending less than nine medical experts could offer causation testimony concerning Sean Pugh). And Defendant Dr. Sabouni further argues Plaintiffs’ failure to identify an additional medical expert to opine on causation in their initial response to Defendants’ motions for summary judgment should “be interpreted as an admission that Plaintiffs do not have another causation expert.” ECF No. 184 at 3.

and apart from autism) or specific causation (i.e., that as a result of Defendants' negligence, Plaintiffs must prove that HIE was the cause for other alleged "injuries" sustained by [Sean Pugh])." ECF No. 184 at 6. Dr. Sabouni also contends autism is inextricably linked to Dr. Mulkey's opinion concerning neurodevelopmental outcomes.¹⁶

Therefore, Defendants submit Plaintiffs' failure to provide expert opinion on the causation of Sean Pugh's injuries prevents Plaintiffs from meeting the causation element of a *prima facie* claim of professional negligence/medical malpractice. *See* ECF No. 184 at 11. Thus, Defendants contend summary judgment is warranted concerning Plaintiffs' medical malpractice/negligence claims.

2. LEGAL STANDARDS

a. Causation in Medical Malpractice Claims

To prevail on their medical malpractice claims, Plaintiffs must "establish a duty owed by the physician to the patient, a breach of that duty by the physician, that the breach was the proximate cause of the harm suffered, and the damages suffered were a direct result of the harm." *Toogood v. Owen J. Rogal, D.D.S., P.C.*, 824 A.2d 1140, 1145 (Pa. 2003) (quoting *Hightower-Warren v. Silk*, 698 A.2d 52, 54 (Pa. 1997) (finding medical malpractice claims sounding in negligence have the same elements as those in ordinary negligence actions)). And "[b]ecause the negligence of a physician encompasses matters not within the ordinary knowledge and experience of laypersons a medical malpractice plaintiff must present expert testimony to establish the applicable standard of care, the deviation from that standard, causation and the extent of the injury." *Id.* (citing *Hightower-Warren*, 698 A.2d at 54)).

Concerning causation, "[t]he first step is to determine whether the medical expert for the

¹⁶ *Id.* at 7-10. Defendants Easton Hospital and EAOG also contend Dr. Mulkey's opinion concerns "no other . . . 'developmental abnormalities[sic]' other than autism." ECF No. 185 at 14.

plaintiff “could testify to a reasonable degree of medical certainty that the acts or omissions complained of could cause the type of harm that the appellant suffered.” *Qeisi v. Patel*, No. CIV A 02-8211, 2007 WL 527445, at *9 (E.D. Pa. Feb. 9, 2007) (quoting *Mitzelfelt v. Kamrin*, 584 A.2d 888, 894 (Pa. 1990)). And “[s]econdly, the court must ‘determine whether the acts complained of caused the actual harm suffered by the appellant.’” *Id.* (citing *Mitzelfelt*, 584 A.2d at 894). Courts have labeled the dual requirements of causation as “general causation” and “specific causation,” respectively. *See e.g., . In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016) (Zoloft III)) (“General causation is whether a substance [or other factor] is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance [or other factor] caused a particular individual's injury.”) (footnote omitted), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017). In torts claims, “[s]equence matters: a plaintiff must establish general causation before moving to specific causation. Without the predicate proof of general causation, the tort claim fails.” *Qeisi*, 2007 WL 527445, at *9 (quoting *Mitzelfelt*, 584 A.2d at 894). Nevertheless, “[a]s to the second part of the test[(“specific causation”)], Pennsylvania courts apply a ‘relaxed standard,’ requiring only a finding that the physician's action (or omission) was a substantial factor in causing the injury.” *Id.* (quoting *Mitzelfelt*. 584 A.2d at 894).

Plaintiffs in medical malpractice cases may also “proceed[] under a theory of increased risk.” *Neupauer v. United States , Dep't of Veteran Affs.*, No. 3:15-CV-01903, 2017 WL 6327580, at *29 (M.D. Pa. Dec. 11, 2017) (citing *Hamil v. Bashline*, 392 A.2d 1280, 1287 (Pa. 1978)). So a “medical opinion need only demonstrate, with a reasonable degree of medical certainty, that a defendant's conduct increased the risk of the harm actually sustained, and the jury then must decide whether that conduct was a substantial factor in bringing about the harm.” *Vicari v. Spiegel*, 936 A.2d 503, 510 (Pa. Super. Ct. 2007), *aff'd*, 989 A.2d 1277 (Pa. 2010) (quoting *Smith*, 705 A.2d 894,

899 (Pa. Super. Ct. 1997) (internal quotation omitted)).

In medical malpractice and negligence claims, Plaintiffs often “must present admissible expert testimony” to prove causation because th[ese] case[s] ‘involv[e] complex issues of causation not readily apparent to the finder of fact.’” *Hoefling*, 576 F. Supp. 3d at 270 (quoting *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003)).

b. Admissibility of Expert Opinions

Under the Federal Rules of Evidence, district courts must act as the gatekeepers of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); FED R. EVID. 702. In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court held that “[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” 509 U.S. at 592.

“Before testimony can reach the jury under the cloak of expertise, the Court must evaluate it for three criteria: qualification, reliability and fit.” *Sec. & Exch. Comm'n v. Ambassador Advisors, LLC*, 576 F. Supp. 3d 250, 255 (E.D. Pa. 2021) (citing *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832 (3d Cir. 2020)). First, a witness is **qualified** to provide expert testimony only if the witness has “specialized expertise” in the testimony’s subject matter. *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

Next, a witness’s testimony is **reliable** only if it is founded upon “good grounds.” *UGI Sunbury LLC*, 949 F.3d at 834; FED. R. EVID. 702 (requiring expert testimony be “based on sufficient facts or data” and be derived from “reliable principles and methods” that have been “reliably applied . . . to the facts of the case.”). The U.S. Court of Appeals for “[t]he Third Circuit has interpreted ‘reliability’ to mean that an expert’s testimony is admissible so long as the process

or technique the expert used in formulating the opinion is reliable.” *Elgert v. Siemens Indus., Inc.*, No. CV 17-1985, 2019 WL 1294819, at *5 (E.D. Pa. Mar. 20, 2019) (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (internal citations omitted)). Accordingly, “[a]n expert's opinion must be ‘based on the methods and procedures of science rather than on subjective belief or unsupported speculation.’” *Daddio*, 650 F. Supp. 2d at 403. And “*Daubert*’s reliability analysis . . . applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion.” *Hoefling*, 576 F. Supp. 3d at 271 (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012)).

So “[a] district court is directed to the following factors to determine the reliability of proposed expert testimony: ‘(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.’” *Daddio*, 650 F. Supp. 2d at 403 (quoting *Schneider*, 320 F.3d at 405 (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 n. 8 (3d Cir. 1994)). “As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process.” *Hoefling*, 576 F. Supp. 3d at 272.

Lastly, a witness’ testimony *fits* a case only if it would help the trier of fact to understand the evidence or determine a fact in issue. *UGI Sunbury*, 949 F.3d at 835 (quoting FED. R. EVID. 702); *see also United States v. Ford*, 481 F.3d 215, 219 n.6 (3d Cir. 2007) (“[F]it is [primarily] a relevance concern.”) (internal quotation marks omitted).

The Rules of Evidence reflect a liberal policy of admissibility, even for expert testimony. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008); *see also Takeda Pharmas. USA, Inc.*

v. *Spireas*, No. CV 17-0452, 2019 WL 9596536, at *1 (E.D. Pa. Sept. 4, 2019). “But expert testimony **must** satisfy the requirements set out above to be admissible.” *Sec. & Exch. Comm'n*, 576 F. Supp. 3d at 255 (emphasis added) (citing *UGI Sunbury LLC*, 949 F.3d at 832-33). “The burden to establish that each requirement is satisfied by a preponderance of the evidence rests with the party offering the expert testimony.” *Id.* (citing *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999)).

c. Summary Judgment

Summary judgment is properly granted when there is “no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). Facts are material if they “might affect the outcome of the suit under the governing law.” *Physicians Healthsource, Inc. v. Cephalon, Inc.*, 954 F.3d 615, 618 (3d Cir. 2020) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). A dispute as to those facts is genuine if the “evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* (quoting *Anderson*, 477 U.S. at 248). “We view all the facts in the light most favorable to the nonmoving party and draw all inferences in that party’s favor.” *Id.* (internal quotation marks and citation omitted). Nevertheless, “. . . if the non-moving party has the burden of proof at trial, that party must set forth facts ‘sufficient to establish the existence of an element essential to that party’s case.’” *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 201 (3d Cir. 2006) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

The party moving for summary judgment must first “identify[] those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). In response, the nonmoving party must “designate specific facts showing that there is a genuine issue for trial.” *Id.* at 324

(internal quotation marks omitted). “The nonmoving party . . . ‘cannot rely merely upon bare assertions, conclusory allegations or suspicions’ to support its claim.” *Schloss v. Sears Roebuck & Co.*, No. 04-CV-2423, 2006 WL 8459575, at *2 (E.D. Pa. Sept. 27, 2006) (quoting *Townes v. City of Phila.*, Civ. A. No. 00-CV-138, 2001 WL 503400, at *2, 2001 U.S. Dist. LEXIS 6056 at *4 (E.D. Pa. May 11, 2001) (internal quotation omitted)). “The mere existence of a scintilla of evidence in support of the [nonmovant’s] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmovant].” *Daniels v. Sch. Dist. of Phila.*, 776 F.3d 181, 192 (3d Cir. 2015) (quoting *Anderson*, 477 U.S. at 252).

3. DISCUSSION

Defendants contend summary judgment is warranted concerning Plaintiffs’ claims of professional negligence/medical malpractice. Defendants aver Plaintiffs cannot establish a cause of action for professional negligence/medical malpractice because the record does not show “the [medical provider’s] breach of duty [of care] was the proximate cause of, or a substantial factor in, bringing about the harm suffered by the patient.” ECF No. 185 at 2 (quoting *Garcia v. United States*, No. 3:17-CV-01910, 2022 WL 19569519, at *3 (quoting *Mitzelfelt*, 584 A.2d at 891); *see also* ECF No. 184 at 5 (providing the same elements of a professional negligence/medical malpractice cause of action)). And moreover, Defendants contend, “[b]ecause the negligence of a physician encompasses matters not within the ordinary knowledge and experience of laypersons a medical malpractice must present expert testimony” ECF No. 185 at 2 (quoting *Toogood*, 824 A.2d at 1145). Thus, summary judgment is warranted concerning Plaintiffs’ claims “[s]ince Plaintiffs have failed to identify any expert, other than Dr. Mulkey, who will opine as to the alleged cause of [Sean Pugh’s] remaining injuries at trial.” ECF No. 184 at 5.

On the other hand, Plaintiffs contend summary judgment is not warranted because the record shows sufficient evidence concerning the medical causation of Sean Pugh’s injuries independent of

his autism. Specifically, Plaintiffs point to the following experts to opine on—and evidence showing—certain injuries: (1) Dr. Mulkey, Dr. Aw-Zoretic, Dr. Shih, and Sean’s MRI records concerning Sean’s hypoxia and HIE-related brain damage; (2) Dr. Mulkey, Sean’s hospital consultation reports by Sean’s medical providers, and Defendants’ experts concerning Sean’s intellectual disabilities; (3) Dr. Pacyon and Dr. Barbaresi concerning Sean’s intellectual disabilities of ADHD; and (4) Dr. Mulkey concerning Sean’s pain and suffering. *See generally* ECF No. 186.

At issue is the sufficiency of Plaintiffs’ evidence on causation. In assessing whether sufficient evidence to demonstrate causation exists, the Court must look only to the evidence before it in the record. *See Berckeley*, 455 F.3d at 201 (3d Cir. 2006) (“[S]ummary judgment is essentially ‘put up or shut up’ time for the non-moving party: the non-moving party must rebut the motion with facts in the record and cannot rest solely on assertions made in the pleadings, legal memoranda, or oral argument.”) (citing *Jersey Cent. Power & Light Co. v. Lacey Twp.*, 772 F.2d 1103, 1109–10 (3d Cir.1985)). Therefore, the Court considers whether the record shows sufficient evidence of causation to create a “genuine dispute as to any material fact.” FED. R. CIV. P. 56(a). First, the Court considers whether Plaintiffs may proffer expert opinion and testimony by Dr. Mulkey, who the Court previously precluded from offering expert opinion on autism causation due to insufficient reliability under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). *See* ECF Nos. 159, 160. Then, the Court will look to the additional experts and other forms of evidence identified by Plaintiffs.

a. Plaintiffs’ Reliance on Dr. Mulkey’s Expert Opinion

Notably, Defendants filed—and the Court granted—*Daubert* motions specifically concerning Dr. Mulkey’s autism causation opinion. *See* ECF Nos. 159, 160 (precluding Dr. Mulkey from providing testimony concerning a general causation opinion that HIE/NE increases risk and/or causes autism or ASD and/or a specific causation opinion that Sean’s HIE/NE caused his

autism/ASD in this case). Now Plaintiffs submit portions of Dr. Mulkey's opinion addressing subject matter outside of the autism causation issue in support of their Opposition to Defendants' Motion for Summary Judgment. *See generally* ECF No. 186.

Defendants have not explicitly challenged the sufficiency of Dr. Mulkey's opinions outside of the autism causation issue. *See* ECF Nos. 118, 125. Nevertheless, the Court is mindful of its role as "gatekeeper[] of expert testimony" under the Federal Rules of Evidence. *Daubert*, 509 U.S. at 589; *see also Kumho Tire*, 526 U.S. at 141; FED R. EVID. 702. Moreover, "only evidence which is admissible at trial may be considered in ruling on a motion for summary judgment." *Farlow v. Conway*, No. 3:20-CV-349, 2021 WL 5989789, at *3 (M.D. Pa. Aug. 5, 2021), *report and recommendation adopted*, No. CV 3:20-349, 2021 WL 5988570 (M.D. Pa. Dec. 17, 2021), *and report and recommendation adopted sub nom. HASHIM FARLOW, Plaintiff v. B. CONWAY, Defendant*, No. CV 3:20-349, 2021 WL 6123989 (M.D. Pa. Dec. 23, 2021) (quoting *Countryside Oil Co., Inc. v. Travelers Ins. Co.*, 928 F. Supp. 474, 482 (D.N.J. 1995)); *see also Bender v. Norfolk S. Corp.*, 994 F. Supp. 2d 593, 599 (M.D. Pa. 2014) ("Although evidence may be considered in a form which is inadmissible at trial, the *content* of the evidence must be capable of admission at trial.") (citing FED. R. CIV. P. 56(c)(2)).

So, Plaintiffs' proffered evidence in response to Defendants' motion for summary judgment presents a threshold issue: although the Court precluded Plaintiffs' causation expert, Dr. Mulkey, from opining on the causation of Sean's autism, Plaintiffs now contend Dr. Mulkey may present expert causation opinions concerning injuries other than Sean's autism. More specifically, Plaintiffs aver Dr. Mulkey sufficiently provides expert opinion on (1) Sean's hypoxia and HIE-related brain damage; (2) Sean's intellectual and/or developmental disabilities not including autism; and (3) Sean's pain and suffering. *See* ECF No. 186 at 3, 13-16, 19-20.

Defendants have not objected to Dr. Mulkey's opinion on this subject matter, but Defendants previously objected to the reliability of Dr. Mulkey's autism causation opinion, which, they aver, is the sole causation opinion offered by Dr. Mulkey. *See* ECF No. 185 at 14-15. And Defendants contend Dr. Mulkey's testimony and opinion are not sufficiently supported. *See* ECF No. 185 at 15.

"The Third Circuit Court has not directly addressed the issue of whether a trial court may make a *Daubert* determination *sua sponte*. However, other courts have permitted such determinations." *Schloss v. Sears Roebuck & Co.*, No. 04-CV-2423, 2006 WL 8459575, at *3 (E.D. Pa. Sept. 27, 2006) (collecting cases). And, "[m]oreover, the Supreme Court has declared that '[t]he trial court must have the same kind of latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether or not that expert's relevant testimony is reliable.'" *Id.* (quoting *Kumho Tire*, 526 U.S. at 152 (1999)). And federal courts have found "[a] district court's *Daubert* inquiry need not take any specific form, and its *sua sponte* consideration of the admissibility of expert testimony is permissible so long as the court has an adequate record on which to base its ruling." *Id.* (quoting *Miller v. Baker Implement Co.*, 439 F.3d 407, 413 (8th Cir. 2006)) (and citing *Jahn v. Equine Svcs., PSC*, 233 F.3d 382, 393 (6th Cir. 2000) ("a district court should not make a *Daubert* determination when the record is not adequate to the task")).

In *Schloss v. Sears Roebuck & Company*, a federal district court in Pennsylvania conducted a *Daubert* analysis *sua sponte* upon consideration of a defendant's motion for summary judgment. No. 04-CV-2423, 2006 WL 8459575, at *1 (E.D. Pa. Sept. 27, 2006). Prior to conducting a *Daubert* analysis of the expert opinion at issue, the district court found "there is more than sufficient information in these sources to make a *Daubert* determination regarding [the] expert['s] testimony."

Id. at *3. The district court found the record sufficient for a *Daubert* determination based on the expert's report, deposition testimony, and prior testimony before an arbitration panel. *Id.* The court also found Plaintiff had "an adequate opportunity to defend the admissibility of [the expert's] testimony" because the issue of the expert's qualification had been raised when the arbitration panel heard the case and in the defendant's motion for summary judgment. *Id.* The district court then analyzed the expert's opinion and testimony to find the expert did not meet the standards under *Daubert* concerning his qualifications nor the reliability of his testimony. *See id.* at *5-6.

Here, the record is sufficient for a *Daubert* analysis. The Court has previously conducted a *Daubert* analysis as to Plaintiffs' expert Dr. Mulkey. *See* ECF Nos. 159, 160. Throughout the Court's previous *Daubert* analysis, the Court considered Dr. Mulkey's expert report and its supplements, Dr. Mulkey's deposition testimony, and extensive briefing from the Parties in this action. Although the Court's previous *Daubert* analysis concerned Dr. Mulkey's opinion on the particular subject matter of autism causation, Plaintiffs' ability to prove causation has been at the center of this matter throughout litigation. *See e.g.*, ECF No. 125 (Defendants' Easton Hospital and EAOG's Motion to Exclude Plaintiffs' Causation Testimony and Summary Judgment Motion for Lack of Causation), ECF No. 132 (Plaintiffs' Response in Opposition to Defendants' Motion to Exclude Plaintiffs' Causation Testimony and Summary Judgment Motion for Lack of Causation), ECF No. 40 (Plaintiffs' Pre-Trial Memorandum identifying witnesses as causation experts). Furthermore, the Parties had the opportunity to submit additional briefing concerning the sufficiency of Plaintiffs' evidence of causation and injury following the Court's Memorandum Opinion and Order precluding Dr. Mulkey's autism causation opinion. *See* ECF No. 159 at 2-3 (directing the Parties to provide supplemental briefing addressing (1) whether Dr. Mulkey remained Plaintiffs' sole causation expert, (2) whether the record supports any allegations Sean Pugh sustained injuries/harm independent of his autism diagnosis, and (3) whether or not the record

supports Plaintiffs' allegations Defendants' alleged negligence proximately caused or increase the risk of harm suffered by Sean Pugh); *see also* ECF Nos. 184, 185, 186 (the Parties' supplemental briefs following the Court's preclusion of Dr. Mulkey's autism causation opinion). Thus Plaintiffs have had an adequate opportunity to defend the sufficiency of Dr. Mulkey's testimony because the sufficiency of Plaintiffs' proffered experts has been fully briefed and is at the crux of this matter.

Because the reliability of Dr. Mulkey's autism causation opinion has been found unreliable and the record is ample on the issue of Dr. Mulkey's sufficiency as an expert on causation, the Court will conduct a *Daubert* analysis of her opinions beyond those precluded in the Court's May 10, 2023 Opinion and Order. In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court held that “[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” 509 U.S. at 592. “Before testimony can reach the jury under the cloak of expertise, the Court must evaluate it for three criteria: qualification, reliability and fit.” *Sec. & Exch. Comm'n*, 576 F. Supp. 3d at 255 (citing *UGI Sunbury*, 949 F.3d at 832. First, a witness is **qualified** to provide expert testimony only if the witness has “specialized expertise” in the testimony’s subject matter. *Schneider*, 320 F.3d at 404. Next, a witness’s testimony is **reliable** only if it is founded upon “good grounds.” *UGI Sunbury*, 949 F.3d at 834; FED. R. EVID. 702 (requiring expert testimony be “based on sufficient facts or data” and be derived from “reliable principles and methods” that have been “reliably applied . . . to the facts of the case.”). So “[a]n expert's opinion must be ‘based on the methods and procedures of science rather than on subjective belief or unsupported speculation.’” *Daddio*, 650 F. Supp. 2d at 403 (E.D. Pa. 2009). A district court shall consider a number of “factors to determine the reliability

of proposed expert testimony.”¹⁷ And experts also “must possess a reasonable degree of scientific certainty regarding their causation opinions.” *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 475 (E.D. Pa. 2014) (Zoloft II)).

Here, **first**, concerning Sean’s hypoxia and HIE-related brain damage, Dr. Mulkey provides a series of opinions on the presence and timing of Sean’s HIE-related brain injury during labor and delivery. *See e.g.*, ECF No. 125-11 at 3-4 (Dr. Mulkey July 30, 2022 expert report) (“Sean Pugh had HIE by the definition included in the Neonatal Encephalopathy and Neurologic Outcome, 2nd Edition, Executive Summary, 2014. . . . Thus, his presentation and neonatal course is entirely consistent with HIE”); *id.* at 4 (“Sean Pugh’s NE-HIE at birth was acute and caused by injury occurring near the time of birth and in the minutes until he was resuscitated”); and *id.* (“The last 1 to 1.5 hours of the labor (after 2130 on 1/23/14 when the caesarean section was called) cumulatively contributed to the injury and his severe presentation of NE at birth, i.e., the longer the duration of exposure to the increasingly hypoxic intrauterine environment, the worse Sean’s acidosis and hypoxemia became.”). Notably, Dr. Mulkey’s opinion on this subject matter does not attempt to establish a causal link between Defendant’s conduct and Sean’s injuries.

But Dr. Mulkey also seems to opine as to the cause of these injuries. For example, Dr. Mulkey avers, “The prolonged labor increased Sean Pugh’s risk of developing HIE in the context

¹⁷ *Daddio*, 650 F.Supp.2d at 403 (quoting *Schneider*, 320 F.3d at 405 (citing *In re Paoli*, 35 F.3d at 742 n. 8)). These factors, among others considered by the district court’s discretion are as follows: ““(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.” *Id.*

of FVM.¹⁸ Had caesarean section delivery been expedited when called at 2130 and Sean Pugh had been delivered close to 2130, he more likely than not would not have had severe HIE-NE and would have a much better and likely normal outcome.”¹⁹ So Dr. Mulkey offers a medical causation opinion that the prolonged labor in this case “increased Sean Pugh’s risk of developing HIE.” ECF No. 125-11 at 5. And Dr. Mulkey further links the caesarean section delivery to Sean’s injury by opining an earlier delivery “more likely than not would not” cause Sean severe HIE-NE. *Id.* The Court will consider these causation opinions.

Dr. Mulkey’s causation opinion concerning the caesarean section delivery and Sean’s HIE-NE runs afoul of *Daubert* in a similar way to her autism causation opinion previously precluded by the Court. *See generally* ECF No. 160. The Court precluded Dr. Mulkey’s opinion on autism causation because her “methodology behind her general causation/association opinion . . . does not amount to scientific ‘principles and methodology’ that open the *Daubert* gate.” ECF No. 160 at 26 (citing *Hoefling*, 576 F. Supp. 3d at 280 (citing *Daubert*, 506 U.S. at 595)). In particular, the Court found Dr. Mulkey’s methodology of reviewing “a ‘sample’ of the literature . . . as well as her ‘general knowledge of the literature’ to support her general causation/association opinion” to be an insufficient methodology under *Daubert*. *Id.* at 25 (internal citation and footnote omitted).

¹⁸ The Court understands “FVM” as an abbreviation of “fetal vascular malperfusion,” which “is diagnosed by the presence of vascular lesions in the muscularized fetal vessels in the placenta and the resultant changes in the downstream villi.” Gayatri Ravikumar et al, *Fetal Vascular Malperfusion (FVM): Diagnostic Implications and Clinical Associations*, 35(23) THE JOURNAL OF MATERNAL-FETAL AND NEONATAL MEDICINE 4526, 4526-4533 (2020), <https://pubmed.ncbi.nlm.nih.gov/33261528/#:~:text=Abstract,changes%20in%20the%20downstream%20villi>.

¹⁹ ECF No. 125-11 at 5. Dr. Mulkey also provides: “Sean had HIE at delivery due to a prolonged period of fetal compromise with resultant ischemic brain injury.” ECF No. 125-9 at 8 (Dr. Mulkey September 29, 2021 expert report).

Here, Dr. Mulkey provides even less support behind her causation opinion Defendants' failure to provide a caesarean delivery increased the risk of Sean's severe HIE-NE. Dr. Mulkey's causation opinion concerning the timing of Sean's caesarean delivery and his HIE-NE is based on her review of Sean's clinical records, information concerning the acute perinatal onset timing of HIE per the *Neonatal Encephalopathy and Neurologic Outcome*, 2nd Edition, Executive Summary, 2014, as well as Dr. Mulkey's "education, experience, and the medical literature." ECF No. 125-11 at 2. But the Court has found expert opinions on causal conclusions necessitate a "scientific methodology" used to form the opinion, such as "examining 'the literature as a whole,'" ECF No. 160 at 23 (quoting *Hoefling*, 576 F. Supp. at 273) (internal quotation omitted), and/or providing "positive and replicated epidemiological studies" in support of the causal opinion, *id.* at 24 (quoting *Hoefling*, 576 F. Supp. at 274-75) (internal quotation omitted). Dr. Mulkey does not otherwise outline a methodology in support of her conclusion. Nor does she provide additional information as to how, in general, the timing of a caesarean delivery can increase the risk of severe HIE-NE. *See Hoefling*, 576 F. Supp. 3d at 270 (quoting *Zoloft III*, 176 F. Supp. 3d at 491) (finding plaintiffs "must establish general causation before moving to specific causation."). Thus Dr. Mulkey's opinion on the increased risk of Sean developing HIE is a specific causation opinion is not sufficiently reliable under *Daubert*.

Next, on the topic of the timing of a caesarean delivery and resulting severe HIE-NE, Dr. Mulkey opines "[h]ad caesarean section delivery been expediated when called at 2130 and Sean Pugh had been delivered close to 2130, he more likely than not would not have had severe HIE-NE and would have a much better and likely normal outcome." ECF No. 125-11 at 5. "Pennsylvania requires experts to testify that defendant's actions caused plaintiff's illness with a reasonable degree of medical certainty." *In re Paoli*, 35 F.3d at 750 (citing *Cohen v. Albert Einstein Medical Ctr.*, 592 A.2d 720, 724 (Pa. Super. Ct. 1991), *appeal-denied*, 602 A.2d 855 (Pa. 1992)). And

“Pennsylvania courts have long drawn a distinction between reasonable certainty and probabilistic guesswork.” *Hoefling*, 576 F. Supp. 3d at 285 (internal citations omitted). “Testimony that something was ‘more likely than not’ the cause of the plaintiff’s injury is insufficient.” *Id.* (citing *Griffin v. Univ. of Pittsburgh Med. Ctr.–Braddock Hosp.*, 950 A.2d 996, 1003 (Pa. Super. Ct. 2008)); *see also id.* (“[A]n expert does not express the requisite certainty when he puts the odds in favor of his theory of causation at just above fifty-fifty.”) (internal citations omitted).

Here, Dr. Mulkey’s opinion an earlier caesarean delivery would render Sean “more likely that not” without severe HIE-NE and with a “likely normal outcome” is not a sufficiently precise medical opinion because it expresses no more certainty than probabilistic guesswork. ECF No. 125-11 at 5. Therefore, Dr. Mulkey’s brief and conclusory causation opinions linking the Defendants’ timing and manner of Mrs. Pugh’s delivery to Sean’s medical outcomes such as HIE-NE and other outcomes are insufficient and will be precluded. The Court will not consider these opinions in determining Defendants’ motion for summary judgment. *See Farlow*, 2021 WL 5989789, at *3 (“[O]nly evidence which is admissible at trial may be considered in ruling on a motion for summary judgment.”).

Second, concerning Sean’s alleged intellectual and/or developmental disabilities not including autism, Dr. Mulkey provides several opinions, such as, “Individuals may have a predisposition that when exposed to additional factors (i.e., prematurity, infection, inflammation, hypoxemia) promote the higher risk of developmental neuropsychiatric disorders.” ECF No. 125-11 at 2. And also “[t]he outcome of hypoxic-ischemic encephalopathy (HIE) includes, ‘other developmental abnormalities,’ beyond cerebral palsy.” *Id.* (providing the following citation: *Neonatal Encephalopathy and Neurologic Outcome*, Executive Summary, 2nd Ed., 2014). Plaintiffs also point to Dr. Mulkey’s opinion “[F]etal exposure to inflammation can affect fetal brain development and function and be a risk factor for abnormal neurodevelopmental outcomes.”

ECF No. 186 at 15-16 (citing ECF No. 142-5 at 10) (Dr. Mulkey Sept. 29, 2021 expert report) (citing Christina N. Cordeiro, Michael Tsimis, & Irina Burd, *Infections and Brain Development*, 70(10) OBSTET GYNECOL SURV. 644, 644-55 (2015), <https://pubmed.ncbi.nlm.nih.gov/26490164/>). On this topic, Dr. Mulkey also provides, “. . . [T]he brain MRI findings of white matter injury that [Sean] has now is consistent with sequelae of the acute HIE he had on his brain MRI at 5 days of age. He has an abnormal neurodevelopmental outcome due to his injury.” ECF No. 125-10 at 2. So Plaintiffs aver Dr. Mulkey provides expert testimony concerning (1) Sean’s neurodevelopmental injuries independent of autism, as well as (2) the general causation of neurodevelopmental injuries resulting from HIE/NE.

But the Court has already ruled Dr. Mulkey has not presented sufficient information concerning her methodology when forming causation opinions. And Dr. Mulkey’s causation opinions concerning abnormal neurodevelopmental outcomes independent of autism are no more supported than her opinions concerning the specific outcome of autism. *See* ECF No. 160 at 23-24 (internal citations and quotations omitted) (finding “scientific methodolog[ies]” behind causal opinions may include an examination of relevant the literature and/or providing “positive and replicated epidemiological studies”). Moreover, Dr. Mulkey’s opinion on abnormal neurodevelopmental outcomes does not attempt to establish a causal link between the Defendants’ conduct and the injuries at issue. *See Toogood*, 824 A.2d at 1145 (internal quotation omitted) (Plaintiffs must “establish a duty owed by the physician to the patient, a breach of that duty by the physician, that the breach was the proximate cause of the harm suffered, and the damages suffered were a direct result of the harm.”); *see also Vicari*, 936 A.2d at 510 (a “medical opinion need only demonstrate . . . that a defendant’s conduct increased the risk of the harm actually sustained”).

Furthermore, although Dr. Mulkey abstractly references multiple “developmental abnormalities” that can occur from HIE/NE, she only explicitly identifies autism as it relates to

Sean's injuries. *See* ECF No. 125-9 at 10 ("Sean had severe neonatal encephalopathy (HIE-type) at birth and has **an abnormal neurodevelopmental outcome of autism**. Had he avoided HIE, his outcome would be normal.") (emphasis added). The focus of Dr. Mulkey's opinion is Sean's abnormal neurodevelopmental outcome **of autism**—any peripheral opinion expanding her causal opinion to other abnormal neurodevelopmental outcomes is incidental, not supported, and insufficient to establish the medical causes of Sean's injuries at this late stage of litigation. *See Berckeley*, 455 F.3d at 201.

And third, concerning Sean's alleged injury of pain and suffering, Plaintiffs aver Dr. Mulkey opines on Sean's pain and suffering relating to his delayed delivery in the following opinion:

Sean Pugh's NE-HIE at birth was acute and caused by injury occurring near the time of birth and in the minutes until he was resuscitated, and his perfusion was restored. The clinical reasons why Sean had acute HIE injury at birth are due to his clinical presentation with severe acidosis, low Apgar scores requiring significant resuscitation, elevation of liver and kidney enzymes, and the pattern of restricted diffusion on the brain MRI at five days of age. . . . the longer duration of exposure to the increasingly hypoxic intrauterine environment, the worse Sean's acidosis and hypoxemia became.²⁰

Dr. Mulkey thus opines Defendant's failure to provide an earlier delivery of Sean by caesarean section led to Sean's increased exposure to "the increasingly hypoxic intrauterine environment," worsening his acidosis and hypoxemia. *Id.* But, once again, Dr. Mulkey does not outline a methodology in support of this conclusion. Nor does she provide additional information as to how, in general, the timing of a caesarean delivery can increase the risk of severe HIE-NE to cause pain and suffering. *See Hoebling*, 576 F. Supp. 3d at 270 (quoting *Zolofit III*, 176 F. Supp. 3d at 491) (finding plaintiffs must proffer a general causation opinion before a specific causation opinion). Therefore, Dr. Mulkey's brief and conclusory causation opinions linking the Defendants' timing

²⁰ ECF No. 186 at 19 (citing ECF No. 142-5 at 3) (Dr. Mulkey July 30, 2022 expert report).

and manner of Mrs. Pugh's delivery to worsening Sean's medical outcomes of HIE-NE and other injuries are insufficient and will be precluded. The Court will not consider these opinions in determining Defendants' Motion for Summary Judgment. *See Farlow*, 2021 WL 5989789, at *3 (finding only admissible evidence may be considered in ruling on a motion for summary judgment).

b. Plaintiffs' Additional Experts Proffered to Provide Medical Causation Evidence and/or Evidence of Sean Pugh's Injuries

The Court will now consider the sufficiency of Plaintiffs' medical causation evidence outside of the expert opinions provided by Dr. Mulkey. The Court will address Plaintiffs' proffered expert opinions and additional evidence identifying several alleged injuries and their causes. First, concerning Sean's alleged hypoxia and HIE-related brain injury, Plaintiffs put forward the following experts and evidence concerning medical causation of the injury: Dr. Aw-Zoretic, Dr. Shih, and Plaintiffs' MRI reports. Next, concerning Sean's neurodevelopmental outcome of ADHD, Plaintiffs put forward expert opinions by Dr. Pacyon and Dr. Barbaresi. And lastly, on the topic of Sean's alleged neurodevelopmental abnormalities outside of ADHD, Plaintiffs point to the following evidence: hospital consultation reports by Sean's primary physicians, as well as Defendant's experts Dr. Enns and Dr. Volkmar.²¹ The Court will consider Plaintiffs proffered evidence as to each injury and their causes in seriatim.

²¹ Because Plaintiffs only provided evidence from Dr. Mulkey's precluded opinions as to Sean's alleged injury of pain and suffering, the Court does not consider this injury in the summary judgment analysis. Plaintiffs must point to specific evidence in response to a summary judgment motion. *See Celotext*, 477 U.S. at 324 (internal quotation marks omitted) (finding, in response to a motion for summary judgment, the nonmoving party must "designate specific facts showing that there is a genuine issue for trial). And because Plaintiffs do not provide an expert to opine as to whether Defendants' conduct medically caused and/or increased the risk of Sean's pain and suffering in this matter, Plaintiffs' evidence of an injury based on Sean's pain and suffering is insufficient. *See Toogood*, 824 A.2d at 1145 (citing *Hightower-Warren*, 698 A.2d at 54) (finding "a medical malpractice plaintiff must present expert testimony to establish the applicable standard of care, the deviation from that standard, causation and the extent of the injury"); *see also Berkeley*, 455 F.3d at 201 ("the non-moving party must rebut the motion with facts in the record and cannot rest solely on assertions made in the pleadings, legal memoranda, or oral argument.").

i. Hypoxia and HIE-Related Brain Damage

In Plaintiffs' supplemental brief, Plaintiffs first aver Sean's hypoxia and HIE-related brain damage is an injury resulting from Defendants' conduct.²² Plaintiffs point to evidence showing Sean was born with HIE²³ and that HIE "occurred acutely during labor and delivery." ECF No. 186 at 8. But, even assuming HIE is a sufficient injury in and of itself, Plaintiffs do not put forward a causation expert to opine on whether Defendants' conduct increased the risk and/or caused HIE. In Plaintiffs' Supplemental brief, they cite to findings of three experts specifically concerning the alleged injury of HIE, including Dr. Aw-Zoretic and Dr. Shih, as well as findings seen in Sean's MRIs.²⁴ Plaintiffs thus aver "the record easily demonstrates that Sean suffers HIE-related brain damage caused by Defendants' untimely delivery." ECF No. 186 at 8. The Court disagrees. Plaintiffs point to evidence showing Sean suffered HIE-related brain damage, and perhaps even that this injury occurred during labor and delivery, but Plaintiffs do not provide expert opinions Defendants' failure to provide an earlier delivery by caesarean section increased the risk of Sean's brain damage.

Plaintiffs first point to neuroradiology expert Dr. Aw-Zoretic who "opines to a reasonable degree of medical certainty that Sean 'suffered an acute profound hypoxic brain injury.'" ECF No. 186 at 7 (citing Dr. Aw-Zoretic expert report, ECF No. 142-6). More specifically, Dr. Aw-Zoretic

²² The Court notes, prior to the Parties' submissions of supplemental briefing, Plaintiffs' theory of injury focused on outcomes resulting from Sean's hypoxia and HIE-related brain injuries, as compared to considering Sean's hypoxia and HIE-related brain injury as an injury in and of itself. *Compare* ECF No. 132 at 42-46 with ECF No. 186 at 7-8.

²³ For further information concerning the definition of HIE, *see supra* n. 4 and accompanying text.

²⁴ As stated, Plaintiffs also put forward Dr. Mulkey as an expert concerning this injury. But the Court will not consider her testimony. For more information on the preclusion of Dr. Mulkey's causation testimony on Sean's HIE-related brain injury, *see supra* pgs. 26-28.

analyzed “all of the imaging for [Sean Pugh] and utilize[ed] [their] many years of medical experience, training, knowledge, and continued clinical experience in th[e] field” to provide interpretations of the MRI and other imaging for Sean Pugh and related findings. *See* ECF No. 142-6 at 11-12. Ultimately, Dr. Aw-Zoretic finds “with a reasonable degree of medical certainty, the changes seen on the MRI on [Sean Pugh’s] day of life [five] shows[sic] a single event versus hypoxic ischemic changes occulting at multiple event[sic] and are indicative of hypoxic ischemic injury on the day of birth.” *Id.* at 17. Dr. Aw-Zoretic thus provides an expert opinion on whether and when Sean experienced a HIE-related brain injury. But, notably, Dr. Aw-Zoretic does not provide a medical causation opinion concerning whether Defendants’ failure to provide an earlier caesarean increased the risk or otherwise caused the types of HIE and related brain injuries suffered by Sean.

Plaintiffs next contend their pathology expert Dr. Shih opines on the medical causation of Sean’s HIE-related brain injury. Plaintiffs contend Dr. Shih “opines to a reasonable degree of medical certainty that Sean suffered acute hypoxia and ischemia due to fetal vascular malperfusion.”²⁵ And Dr. Shih opines “hypoxia occurred acutely during labor and delivery.” ECF No. 186 at 8. Furthermore, Dr. Shih provides “there was ‘vascular malperfusion’ in Mrs. Pugh’s placenta that led to ‘the bad outcome of the fetus after delivery,’ as fetal vascular malperfusion ‘lead[s] to . . . hypoxic conditions’ in the fetus.” *Id.* (internal citations omitted). As with Dr. Aw-Zoretic, Dr. Shih’s opinions are helpful in establishing Sean suffered hypoxia and ischemia during labor and delivery. But Dr. Shih does not offer any explanation as to the medical causes of those

²⁵ ECF No. 186 at 8 (citing Dr. Shih expert report, ECF No. 142-1). The Court notes fetal vascular malperfusion “is the most recent term applied to a group of placental lesions [t]he common etiology [of which] is umbilical cord obstruction.” Raymond W. Redline & Sanjita Ravishankar, *Fetal Vascular Malperfusion, an Update*, 126(7) APMIS 561, 561-69 (2018), <https://pubmed.ncbi.nlm.nih.gov/30129125/>.

injuries—and whether Defendants' conduct increased the risk and/or otherwise caused these injuries. Thus, Plaintiffs have not produced sufficient expert evidence concerning how Defendants' conduct in failing to provide an earlier caesarean section increased the risk or otherwise caused the types of HIE and related brain injuries suffered by Sean.²⁶ In conclusion, Plaintiffs do not offer experts to opine on the medical causation of Sean's HIE-related brain injury.

²⁶ *Vicari v. Spiegel*, 936 A.2d 503, 510 (Pa. Super. Ct. 2007), *aff'd*, 989 A.2d 1277 (Pa. 2010) (quoting *Smith*, 705 A.2d 894, 899 (Pa. Super. Ct. 1997) (internal quotation omitted) (looking to whether defendants' conduct "increased the risk of the harm actually sustained, and [thus necessitating] the jury . . . must decide whether that conduct was a substantial factor in bringing about the harm."). The Court notes, in response to a summary judgment motion, the nonmoving party must "designate specific facts showing that there is a genuine issue for trial." *Celotex Corp.*, 477 U.S. at 324 (internal quotation marks omitted). Here, Plaintiffs identified the opinions of three experts (Dr. Mulkey, Dr. Aw-Zoretic, and Dr. Shih) and MRIs in response to the Defendants' motion for summary judgment on medical causation. In addition, Plaintiffs outlined the opinions of Marc H. Kobelin, M.D., Ana M. Lobo, M.D., MPH, and Susan Abookire, M.D., FACP, MPH, concerning Defendants' negligence.

First, Plaintiffs proffer Dr. Kobelin to provide expert opinion as to liability. *See* ECF No. 142 at 5 (Plaintiffs' Pretrial Memorandum). Following an analysis of the facts of the case, Dr. Kobelin provides six "conclusions within a reasonable degree of medical certainty with respect to the specific deviations from the standard of care provided to Ms. Pugh." ECF No. 142-2 at 4. Dr. Kobelin further opines Defendants' "... care provided was below the standard of care." *Id.* And thus, according to Dr. Kobelin, "[t]he deficiencies noted in the interpretation of the fetal heart rate resulted in undue delay of delivery and **allowed** baby Sean to become hypoxic and acidotic which resulted in his injuries." *Id.* Dr. Kobelin does not provide any supporting information concerning how he reaches this conclusion, or any explanation as to how a delayed caesarean section can increase the risk and/or cause a baby in Sean's position to become hypoxic and result in brain injuries. Dr. Kobelin's testimony focuses on the standard of care for doctors—Dr. Kobelin does not provide a causal opinion concerning Defendants' conduct increasing the risk of HIE-related brain injuries besides his conclusion. Moreover, the phrasing of Dr. Kobelin's opinion is not sufficiently precise under Pennsylvania law concerning medical causation opinions. *In re Paoli*, 35 F.3d at 750 (internal citation omitted) ("Pennsylvania requires experts to testify that defendant's actions caused plaintiff's illness with a reasonable degree of medical certainty.").

And, to the extent Dr. Kobelin makes a causation opinion concerning the impact of Defendants' conduct, this conclusion is not sufficiently supported. *See Zoloft II*, 26 F. Supp. 3d at 475 ("To meet the Daubert standard, the experts must demonstrate that these opinions are based on methods and procedures of science, not speculation or subjective belief, and they must possess a reasonable degree of scientific certainty regarding their causation opinions."); *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 2:10CV143, 2014 WL 814878, at *6 (W.D. Pa. Feb.

Lastly, Plaintiffs contend “Sean’s birth-related brain damage . . . [is] confirmed repeatedly on MRI imaging” ECF No. 186 at 1; *see also id.* at 7 (describing findings of Sean’s day-5 MRI and MRS, as well as MRI findings from January 28, 2022). But, as stated, medical malpractice and negligence claims often require Plaintiffs “‘present admissible expert testimony’ to prove causation because th[ese] case[s] ‘involv[e] complex issues of causation not readily apparent to the finder of fact.’” *Hoefling*, 576 F. Supp. 3d at 270 (E.D. Pa. 2021) (quoting *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003)). Here, Plaintiffs must establish whether the medical procedures employed by Defendants increased the risk and/or proximately caused Sean’s injuries. Thus Plaintiffs shall present expert opinion and testimony on this highly scientific and medical topic of professional negligence and medical causation that is otherwise not readily

27, 2014) (“The proponent of the evidence must show . . . that ‘the expert’s conclusion has been arrived at in a scientifically sound and methodologically reliable fashion’”) (citing *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)). Thus Dr. Kobelin’s does not provide a sufficient medical causation opinion concerning whether Defendants’ conduct increased the risk and/or caused Sean’s medical outcomes.

Plaintiffs also proffer Dr. Lobo and Dr. Abookire as experts on Defendants’ liability. More specifically, Plaintiffs contend “Dr. Lobo opines primarily on Defendants’ failure to assemble the hospital anesthesiologist and other personnel following the C-section order.” ECF No. 186 at 22 (citing Dr. Lobo expert report, ECF No. 142-4 at 2-4). As Plaintiffs aver, Dr. Lobo “ultimately concludes that Defendants’ failures to notify the anesthesiologist and other personnel of the C-section order ‘was below the standard of care.’” *Id.* (citing ECF No. 142-14 at 2-3). Notably, Dr. Lobo does not opine on the medical causation of Sean’s resulting injuries as a result of Defendants conduct. And, as Plaintiffs further contend, another expert, Dr. Abookire, ‘similarly opines that Defendants breached the standard of care by failing to timely deliver Sean via C-section.’” ECF No. 186 at 23 (citing Dr. Abookaire expert report, ECF No. 142-3). After considering the factual circumstances surrounding Mrs. Pugh’s labor, Dr. Abookire opines Defendants’ “failure to have an effective communication protocol for calling a C-section caused a delay in the delivery of Sean Pugh.” *Id.* In support of her opinion concerning Defendants’ conduct in this case in relation to the appropriate standard of care, Dr. Abookire provides her opinion addresses the issue “as to whether Easton Hospital met the standard of care by[sic] in the care of Ms. Ashley Pugh and her child, Sean Pugh.” ECF No. 142-3 at 3. Like Dr. Lobo, Dr. Abookie does not purport to offer an opinion concerning medical causation, let alone an opinion concerning the causation of Sean Pugh’s HIE-related brain injury. *See generally id.*

apparent to the finder of fact. *See id.* Therefore, evidence in the form of MRI imagining, absent expert opinion, is not sufficient to show causation.

ii. Neurodevelopmental Impairments of ADHD

Plaintiffs also provide experts opining on Sean Pugh's neurodevelopmental impairments of ADHD. *See* ECF No. 186 at 10-13. Two experts proffered by Plaintiffs, Dr. Pacyon, and Dr. Barbaresi, opine as to Sean's ADHD diagnosis as well as other neurodevelopmental delays. *See id.* at 10-11. More specifically, Plaintiffs contend Dr. Pacyon opines "Sean meets the clinical criteria for the neurodevelopmental impairments of ADHD" *Id.* at 10. Dr. Pacyon also "diagnosed Sean with ADHD" due to her various behavioral observations. *Id.* Similarly, Dr. Barbaresi "opines that Sean 'fulfills diagnostic criteria for [ADHD]'" *Id.* at 11 (citing ECF No. 142-7 (Dr. Barbaresi January 30, 2022 expert report)). Plaintiffs further aver "Drs. Pacyon and Barbaresi also summarize Sean's history of neurodevelopmental delays that commenced immediately after birth." *Id.* (citing ECF No. 142-8).

Although Plaintiffs' experts Dr. Pacyon and Dr. Barbaresi opine as to Sean's neurodevelopmental injuries of ADHD, Plaintiffs do not proffer Dr. Pacyon nor Dr. Barbaresi as experts on the **cause** of these injuries. *See* ECF No. 186 at 8-13. Accordingly, Plaintiffs do not provide sufficient causation evidence concerning this injury.

iii. Other Neurodevelopmental Abnormalities or Impairments Independent of ADHD

Plaintiffs also contend the record shows Sean's injuries of intellectual disabilities/deficits outside of autism, as well as the causation of these injuries. First, Plaintiffs point to hospital consultation reports completed by a variety of Sean's medical providers. ECF No. 186 at 8-9. But, even assuming these consultation reports are not hearsay and thus admissible, Plaintiffs are still required to present expert testimony on the causation of these injuries not readily apparent to the

finder of fact. *See Hoeftling*, 576 F. Supp. 3d at 270 (quoting *Soldo*, 244 F. Supp. 2d at 525). So hospital consultation reports, absent expert opinion, are not sufficient to show causation.

Next, Plaintiffs submit Defendants' own experts opine as to Sean's neurodevelopmental abnormalities and "agree that HIE could cause the type of neurodevelopmental abnormalities that Sean suffered/suffers."²⁷ First, Plaintiffs largely point to the deposition transcript of Dr. Enns, an expert proffered by Defendant. Plaintiffs aver Dr. Enns opines in agreement with a variety of statements posed by Plaintiffs' counsel, such as: "[Neonatal hypoxia ischemic encephalopathy] is one of the leading causes of infant mortality globally with survivors being at an increased risk of disability and major neurologic sequela[;]"²⁸ "research show[s] 'encephalopathy that accompanies hypoxic ischemia may have subtle affects[sic] on the development of the brain producing a long-term impact on intellectual function in children without a marked structural damage to the deepgray matter [or] the frontal white matter[;]" and "research show[s] perinatal asphyxia or hypoxia "has been shown to result in cognitive assessment scores of children that are significantly lower than healthy children;" that children with severe HIE "are at risk for core neuro-development outcomes in their early years;" and that "children with HIE and who have learning disabilities are likely to face problems in school throughout the course of their education." ECF No. 186 at 16 (internal citations omitted). But also in Dr. Enns' deposition, Dr. Enns explicitly provides "[his] opinions in this case are related to solely the etiology of autism, and [he's] not offering any opinions regarding the etiology of [Sean's] intellectual disabilities." ECF No. 132-1 at 23, Enns Dep. Tr. 87:6-25. Dr.

²⁷ ECF No. 186 at 16. For the purposes of this analysis, the Court assumes—but declines to find as a matter of law—Plaintiffs may rely upon expert testimony of an opposing party at the summary judgment stage. *See House v. Combined Ins. Co. of Am.*, 168 F.R.D. 236, 245 (N.D. Iowa 1996) ("[O]nce an expert is designated, the expert is recognized as presenting part of the common body of discoverable, and generally admissible, information and testimony available to all parties.").

²⁸ In Dr. Enns' deposition, this statement is read by Plaintiffs' counsel followed by the question posed to Dr. Enns: "Do you agree with that?" ECF No. 132-1, Enns Dep. Tr., 185:14-19. In response, Dr. Enns provided, "I do, yes." *Id.*

Enns also answers negatively to Plaintiffs' counsel's question, "Are we in agreement then, based upon the statement that you just gave us, that Sean's HIE is the[sic] responsible for his neurocognitive deficits, setting autism aside?" *Id.*, Enns Dep. Tr. 85:6-22. Thus, contrary to Plaintiffs' averments, Dr. Enns does not proffer expert testimony that HIE could cause neurodevelopmental abnormalities independent of autism.

Plaintiffs also point to the deposition transcript of Dr. Volkmar, another of Defendant's experts. Plaintiffs contend Dr. Volkmar provides a causation opinion as to Sean's intellectual and other developmental disabilities outside of autism. More specifically, Dr. Volkmar responded in agreement with Plaintiffs' counsel's question of whether "apnea or respiratory distress can cause stand-alone intellectual disability." ECF No. 132-2 at 33, Volkmar Dep. Tr. 123: 17-25. Furthermore, in response to Plaintiffs counsel's question "Are we in agreement that Sean Pugh's hypoxia caused his cognitive and sensory-motor impairments?[,]" Dr. Volkmar responded over the objection of counsel "I think we can agree that they may contribute to some of his cognitive and learning challenges." *Id.* at 25, Volkmar Dep. Tr. 90: 13-22. Plaintiffs also point to the findings in Dr. Volkmar's expert reports; specifically, Dr. Volkmar found one study's conclusion "shows a much stronger connection of significant neonatal hypoxia to intellectual disability than to autism." ECF No. 121-2 at 8 (Dr. Volkmar expert report). But Dr. Volkmar also explicitly declines to offer a causal opinion on intellectual disabilities outside of autism. ECF No. 132-2, Volkmar Dep. Tr. 84:2-25, 85: 1-12 (declining to offer a causal opinion on intellectual disabilities outside of autism due to the focus of his expertise "on the autism world" and not intellectual disabilities more generally).

The reports and testimony of Dr. Enns and Dr. Volkmar do not present sufficient evidence a reasonable jury could conclude Sean's HIE at birth caused his intellectual, cognitive, and other

developmental injuries. Plaintiffs point to responses provided by Dr. Enns and Dr. Volkmar in their deposition testimony. And both experts decline to provide a causal opinion concerning the cause of Sean Pugh's abnormal developmental outcomes outside of autism. *See* ECF No. 132-1 at 23, Enns Dep. Tr. 87:6-25 (clarifying his proffered opinion on the etiology of autism and not the etiology of other intellectual disabilities); ECF No. 132-2, Volkmar Dep. Tr. 84:2-25, 85: 1-12 (limiting his expertise to "the autism world" and not intellectual disabilities more generally). And, furthermore, both Dr. Enns and Dr. Volkmar merely provide brief, unsupported responses in agreement with Plaintiffs' counsel's questions. And courts shall not consider conclusory statements without supporting analysis. *See* MICHAEL H. GRAHAM, HANDBOOK OF FEDERAL EVIDENCE (9th ed. 2022) ("The explanatory theory must be supplied by the expert; an opinion without analysis is meaningless.") (collecting cases); *see also* e.g., *Mid-State Fertilizer Co. v. Exch. Nat. Bank of Chicago*, 877 F.2d 1333, 1339 (7th Cir. 1989) ("An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.") (citing *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 829–32 (D.C.Cir.1988)). Therefore, a reasonable jury could not conclude Sean's HIE-related brain injury caused developmental or intellectual abnormalities or impairments independent of autism based on evidence proffered by Defendants' experts Dr. Enns and Dr. Volkmar concerning medical causation. Plaintiffs do not proffer sufficient evidence as to the medical causes of Sean's developmental outcomes independent of autism.

Therefore, Plaintiffs have not proffered sufficient evidence on the medical causation of Sean Pugh's alleged injuries. Because causation is a required element of professional negligence/medical malpractice claims, summary judgment is warranted as to Plaintiffs' claims. *See* *Berkeley*, 455 F.3d at 201 ("... if the non-moving party has the burden of proof at trial, that party must set forth facts 'sufficient to establish the existence of an element essential to that party's case.'") (quoting

Celotex, 477 U.S. at 322)). Defendants' Motion for Summary Judgment for Lack of Causation (ECF No. 125) is granted.

4. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment for Lack of Causation (ECF No. 125) is granted. An appropriate Order follows.

BY THE COURT:

/s/ John M. Gallagher _____

JOHN M. GALLAGHER

United States District Court Judge